



12-21-06

Docket No: AM101032  
Patent

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of: **GREENBERGER et al.**  
Application No.: **10/666,722** Group Art No.: **1614**  
Filed: **September 18, 2003** Examiner: **Timothy E. Betton**  
For: **METHOD OF TREATING RESISTANT TUMORS**  
Confirmation No.: **9014**  
Customer Number: **25291**

Mail Stop Amendment  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**RESPONSE**

This is in response to the Office Action dated 11/24/2006 in the above-identified application.

The Examiner has required restriction to one of two groups:

Group I. Claims 1-68 and 73-81, drawn to a method of treating, inhibiting the growth of or eradicating a tumor in a mammal, classified in class 514, subclass 676.

Group II. Claims 69-72, drawn to a process for the preparation of a carboxylic acid used in the method of Group I, classified in class 514, subclass 676.

Applicants provisionally elect Group I with traverse. For the following reasons, Applicants request withdrawal of the restriction requirement.

Restriction is not appropriate where it would not be a significant burden for the Examiner to search and examine two Groups together. Here the Examiner has stated that both Groups are in the same class and subclass. Therefore, it would not be a significant burden to search and examine both together. It cannot be efficient for the Examiner to search the subclass for one Group, ignoring the other, only to have another Examiner search the same subclass again for the other Group.

**CERTIFICATE OF MAILING 37 CFR §1.10**

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number **EV 971763283 US** addressed to the Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

December 20, 2006  
Date

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To have Applicants file a second patent application for the non-elected Group would be an unnecessary burden on Applicants both by increasing expenses and by increasing the amount of time Applicants will need to spend in the pursuit of two patents instead of one. The Office would also have to duplicate its work, increasing the backlog of cases, contrary to the Office's goal of reducing backlog. Furthermore, the public would be burdened by having two patents to consider instead of one in any infringement analysis.

The Examiner has failed to explain why it is reasonable to impose these additional burdens on the Office, the Applicants and the public, in view of the insignificant burden the Examiner would carry by keeping both Groups together in this application. The Examiner has also failed to clearly explain why the two Groups are "distinct by design"; no explanation of the reasoning which led to that conclusion has been provided by the Examiner.

The Examiner has requested election of a species for Group I. Applicants elect the species of Example 57: N,O, $\beta$ , $\beta$ -tetramethyl-L-tyrosyl-N<sup>1</sup>-[(1S,2E)-3-carboxy-1-isopropyl-2-butenyl]-N<sup>1</sup>,3-dimethyl-L-valinamide. Claims 1-15, 19, 21-28, 39, 49, 51-59 and 73-81 are believed to be readable on this species.

The Examiner has further required an election of a chemotherapy agent/antimicrotubule inhibitor or combination which will be administered with the elected species. Applicants elect paclitaxel. All the claims in Group I are believed to be readable on this species.

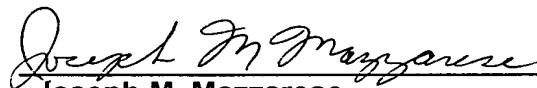
The Examiner also has required election of a tumor disease/condition. Applicants elect ovarian tumors, with traverse. Applicants believe that this requirement is unnecessary and does not significantly reduce the Examiner's search burden. Once the search has been limited to the compound species elected above, the inclusion of the various types of tumors is not a significant burden; the Examiner would likely search through and consider all the references which include the combination of species elected for any tumor disease/condition whether or not one tumor disease/condition is elected. All the claims in Group I are believed to be readable on this species.

The Examiner has required yet another election: Applicants are asked to elect one regimen species, i.e., treatment with the formula II compound before, concurrently with, or after the chemotherapeutic agent. Applicants provisionally elect treatment with the formula II compound after the chemotherapeutic agent, with traverse. No reason is seen to require

this election. The Examiner will not have a reduced search burden as a result of such election. All the claims in Group I are believed to be readable on this species.

The Examiner has also provided an additional species election requirement. However, this requirement appears to be a request for definitions rather than a request for an election of species. If the Examiner wants Applicants to elect something here, Applicants request that the Examiner clarify the request. As for the requested definitions, Applicants believe that these terms are clear to those skilled in the art from the specification and from the ordinary usage in the art.

Applicants believe that this constitutes a complete response to the Office Action. No fee is believed due herewith, but should any fee be due, it may be charged to Deposit Acct. No. 01-1425.



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